Optimal DCB Outcomes
LEVANT 2 and Global SFA
Real-World Registry

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Potential conflicts of interest

Speaker’s name: Andrej Schmidt
✓ I have the following potential conflicts of interest to report:
Consulting:
- Medtronic, Abbott, Boston Scientific, Cook,
- Cordis, C.R.Bard, Intactvascular, ReFlow Medical,
- Spectranetics, Upstream Peripheral

LEVANT 2 Primary Patency

DCB Mechanism of Action

Mechanical (vessel recoil and negative remodeling) and biological response (smooth muscle cell proliferation) due to injury during PTA leads to restenosis

Good Mechanical PTA + Good Drug Delivery = Optimal Outcomes

Was Balloon-Angioplasty in the LEVANT 2 Trial optimally performed?

LEVANT 2 Clinical Trial Average
0.9:1 Balloon to Artery Ratio

LEVANT 2 Full Wall Apposition Sub Group
≥1.04:1 Balloon to Artery Ratio

Full Wall Apposition Showed Increased Primary Patency at 12 Months

Optimal Drug Delivery and DCB Outcomes

DCB Outcomes Influenced by:
✓ Balloon Transit Time
✓ Balloon Inflation Pressure
✓ Balloon Inflation Time
✓ Final % Diameter Stenosis

Indicators from Levant 2 Data Analysis
LEVANT 2 DCB Procedural Variable Analysis

DCB 12 M Primary Patency:
- Improved with 3 variables
- Optimal with variables

LEVANT 2 PTA Procedural Variable Analysis

Optimal Angioplasty procedure with no drug results in 53% Primary Patency

German Sub-Group Analysis

Confirmation of Procedural Variables And Outcomes

Angiographic Characteristics
German vs. non-German Cohorts

Procedural Characteristics
German vs. non-German Cohorts

German DCB Procedural Variables
Primary Patency Kaplan Meier

<table>
<thead>
<tr>
<th>Efficacy Primary Patency</th>
<th>Lutonix DCB (%)</th>
<th>Standard PTA (%)</th>
<th>Difference</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>@365 days</td>
<td>79.4%</td>
<td>97.8%</td>
<td>21.6%</td>
<td>0.015</td>
</tr>
</tbody>
</table>

Freedom from TLR Kaplan Meier

<table>
<thead>
<tr>
<th>Efficacy Primary Patency</th>
<th>Lutonix DCB (%)</th>
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<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>@365 days</td>
<td>96.1%</td>
<td>82.8%</td>
<td>0.012</td>
</tr>
</tbody>
</table>

Global SFA Real-World Registry 12 Months

Final Confirmation Procedural Variables and Outcomes

Global SFA Registry Procedural Analysis

Balloon Inflation Pressure (Atm)

- LEVANT 2: 7.8
- Global SFA: 9.7

Final % DS

- LEVANT 2: 14.6
- Global SFA: 20.9

Lutonix Global SFA Real-World Registry 12 Month Results

<table>
<thead>
<tr>
<th>Measure</th>
<th>Lutonix DCB % (n/N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from TLR</td>
<td>94.3% (595/631)</td>
</tr>
<tr>
<td>30 Day Safety</td>
<td>99.7% (677/678)</td>
</tr>
</tbody>
</table>

Summary

- Optimal Drug Delivery and DCB Outcomes are influenced by procedural variables
  - Balloon Transit time
  - Balloon Inflation Pressure
  - Balloon Inflation Time
  - Final % Diameter Stenosis
- German cohort confirm that good DCB procedures result in durable long term clinical benefits
- Global SFA Registry outcomes confirm good procedures result in optimal outcomes